510(k) Summary

JUL 30 2012

Proprietary Name:	Hip Systems
Common Name:	Artificial Hip Replacement Components –Acetabular and Femoral
Classification Names And References:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis21 CFR §888.3358 Hip joint metal/polymer constrained cemented or uncemented prosthesis.21 CFR §888.3310 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis 21 CFR §888.3353 Hip joint metal/polymer semi-constrained cemented prosthesis 21 CFR §888.3350 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis 21 CFR §888.3360 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis 21 CFR §888.3390
Proposed Regulatory Class:	Class II
Product Codes:	LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented KWZ - prosthesis, hip, constrained, cemented or uncemented, metal/polymer LZO - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented MEH - prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented LWJ - prosthesis, hip, semi-constrained, metal/polymer, uncemented KWL - prosthesis, hip, hemi-, femoral, metal MAY - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous cemented, osteophilic finish KWY - prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented MBL- prosthesis, hip, semi-constrained, uncemented, metal/polymer, porous

For Information contact: Karen Ariemma, RAC
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Date Prepared: July 29, 2012

Description:
The devices included in this submission are femoral stems, femoral heads, acetabular shells, acetabular inserts, modular necks, modular stems and accessory components used in hip arthroplasty procedures. All devices have been previously deemed substantially equivalent in prior 510(k) submissions and are commercially available. The purpose of this submission is to modify the labeling of these devices to include safety information in the Instructions for Use (IFUs) regarding modular hip stem junctions. In addition to this specific update, general revisions have been made to the IFUs to harmonize the language between the Howmedica Osteonics' hip stem labeling

Intended Use:
The hip system devices included in this submission are sterile, single-use devices intended for use in primary and revision total hip arthroplasty to alleviate pain and restore function.

Indications:

The overall indications for use for the subject total and hemi hip replacement prostheses include:

1. noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and,
5. treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The Rejuvenate Hip System is intended for cementless use only.

Additional indications specific to the Hipstar Stem:
The Hipstar Femoral Stem is intended for cementless use only.

When mated with a constrained acetabular liner the Hipstar Stem is indicated for use in primary and revision total hip arthroplasty for patients at high risk of hip dislocation due to a history of prior dislocations, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

Additional indications specific to the Restoration Modular Hip System:
The Restoration Modular Hip System is intended for primary and revision total hip arthroplasty as well as in the presence of severe proximal bone loss. These femoral stems are designed to be press fit into the proximal femur.

Substantial Equivalence:
The subject hip system devices have been deemed substantially equivalent to other commercially available hip arthroplasty systems based upon an evaluation of intended use, design, materials, and operational principles in prior 510(k) submissions. The purpose of this submission is solely to revise the labeling to add safety information regarding modular hip stem taper junctions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 30 2012

Howmedica Osteonics Corp.
% Ms. Karen Ariemma
Senior Strategic Regulatory Affairs Manager
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K121308
Trade/Device Name: Hip Systems
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, KWZ, LZO, MEH, JDI, LWJ, KWL, MAY, KWY, MBL
Dated: April 30, 2012
Received: May 1, 2012

Dear Ms. Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121308 (pg 1/1)

Device Name: Stryker Hip Systems

Indications for Use:

The overall indications for use for the subject total and hemi hip replacement prostheses include:

1. noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. rheumatoid arthritis;
3. correction of functional deformity;
4. revision procedures where other treatments or devices have failed; and,
5. treatment of nonunion, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

The Rejuvenate Hip System is intended for cementless use only.

Additional indications specific to the Hipstar Stem:
The Hipstar Femoral Stem is intended for cementless use only.

When mated with a constrained acetabular liner the Hipstar Stem is indicated for use in primary and revision total hip arthroplasty for patients at high risk of hip dislocation due to a history of prior dislocations, bone loss, joint or soft tissue laxity, neuromuscular disease or intraoperative instability.

Additional indications specific to the Restoration Modular Hip System:
The Restoration Modular Hip System is intended for primary and revision total hip arthroplasty as well as in the presence of severe proximal bone loss. These femoral stems are designed to be press fit into the proximal femur.

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) 510(k) Number (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)